Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

Mekinist (trametinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Mekinist (trametinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Mekinist (trametinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of Central Nervous System (CNS) Cancer (NCCN 2A); **AND**
   A. Individual is using in combination with dabrafenib for one of the following:
      1. Individual has a primary diagnosis of melanoma and disease has metastasized to the brain; **OR**
      2. Individual is using as adjuvant therapy for primary CNS cancer;

OR

II. Individual has a diagnosis of unresectable or metastatic malignant Melanoma (Label, NCCN 1, 2A); **AND**
   A. Individual is using as monotherapy; **AND**
      1. Individual has not been previously treated with a BRAF inhibitor;

   OR

   B. Individual is using in combination with dabrafenib; **AND**
   C. Individual has either BRAF V600E or V600K mutation (or BRAF V600 activating mutation), with test result confirmed;

OR

III. Individual has a diagnosis of melanoma; **AND**
   A. Individual is using in combination with dabrafenib; **AND**
   B. Individual is using as adjuvant treatment; **AND**
   C. Individual has disease involvement of lymph node(s), following complete resection or wide excision; **AND**
   D. Individual has either BRAF V600E or V600K mutation with test result confirmed;

OR

IV. Individual has a diagnosis of metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**
   A. Individual is using in combination with dabrafenib; **AND**

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

B. Individual has BRAF V600E mutation with test result confirmed;

OR

V. Individual has a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC); **AND**
   A. Individual is using in combination with dabrafenib; **AND**
   B. Individual has no satisfactory locoregional treatment options; **AND**
   C. Individual has BRAF V600E mutation with test result confirmed;

OR

VI. Individual has a diagnosis of metastatic or unresectable Uveal Melanoma (NCCN 2A); **AND**
   A. Individual is using as monotherapy.

Key References:

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 7, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Gershenson DM, Miller A, et al. A randomized phase II/III study to assess the efficacy of trametinib in patients with recurrent or progressive low-grade serous ovarian or peritoneal cancer [abstract]. *Ann Oncol*. 2019;30 (suppl_5): abstr LBA61.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 7, 2020.
   a. Central Nervous System Cancers. V2.2020. Revised April 30, 2020.
   b. Cutaneous Melanoma. V3.2020. Revised May 18, 2020.
   c. Non-Small Cell Lung Cancer. V6.2020. Revised June 15, 2020.
   d. Thyroid Carcinoma. V1.2020. Revised June 12, 2020.
   e. Uveal Melanoma. V1.2020. Revised May 21, 2020.
8. Marks AM, Bindra RS, DiLuna ML, et al. Response to the BRAF/MEK inhibitors dabrafenib/trametinib in an adolescent with a BRAF V600E mutated anaplastic ganglioglioma intolerant to vemurafenib. *Pediatr Blood Cancer*. 2018;65(5):e26969.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.